

REMARKS/ARGUMENTS

Claims 1-13 are pending in the application. All claims stand rejected. Claims 7-11 are rejected under 35 U.S.C. §112, first paragraph; Claim 6 is rejected under 35 U.S.C. §112, second paragraph; claims 7-11 are rejected under 35 U.S.C. §112, second paragraph; claims 1-6 and 7-11 are rejected under 35 U.S.C. §103(a) over Keller et al. in view of Ueda et al.; and claims 7-13 are rejected under 35 U.S.C. §103(a) over Blum in view of Keller et al. Applicant respectfully traverses each of these rejections for the following reasons and requests that they be withdrawn in light of the present amendment and remarks.

Claims 7-11 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for treating headaches and anxiety, does not reasonably provide enablement for any condition or disorder. Applicant has amended claim 7 (and hence claims 8-11 depending therefrom) to recite that the subject being treated has neurotransmitter over-stimulation. Therefore, it is believed that this rejection is now moot in light of the present amendment and it is requested that this rejection be withdrawn.

Claim 6 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the claim includes "an additional therapeutic moiety" and it is unclear whether the additional compound is required or a modification of the active compound is required. Applicant has amended claim 6 to clarify that the additional therapeutic moiety is an additional compound. In light of this amendment, applicant requests that the rejection be withdrawn.

Claims 7-11 are rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential elements because the conditions to be treated by the claimed method are not disclosed in the claims. As set forth above, applicant has herein amended claims 7-11 to recite the conditions to be treated by the claimed method and, therefore, it is submitted that this rejection is now moot and should be withdrawn.

Claims 1-6 and 7-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Keller et al. (US 5,891,465) in view of Ueda et al. (US6,589,566). Applicant respectfully traverses this rejection and requests that it be withdrawn for the following reasons.

Keller et al. teaches delivery of biologically active material in a liposomal formulation for administration into the mouth but does not teach delivery of theanine or 5-Hydroxytryptophan. Keller et al. teaches liposomal compositions but does not teach or suggest a liposomal composition comprising theanine or a liposomal composition comprising theanine and 5-hydroxytryptophan. Keller et al. completely fails to teach or suggest the administration of a composition comprising theanine to treat a subject having neurotransmitter over-stimulation.

The deficiencies of the teaching of Keller et al. are not provided by the teachings of Ueda et al. which is directed to compositions for suppressing or ameliorating a symptom accompanying diminished homeostasis. Ueda teaches use of compositions comprising theanine but not liposomal compositions.

Of course, applicant readily admits that liposomal compositions were known before his invention and that compositions comprising theanine were known before his invention. What was not known was a liposomal composition comprising a liposomal encapsulated aqueous solution of an effective amount of theanine and its use to sublingually treat subjects suffering from neurotransmitter over-stimulation.

Applicant has discovered a composition and method which provides focused and surprisingly effective results. The use of a liposomal spray sublingual delivery system quickly delivers an effective amount of theanine yet requires a relatively small amount of theanine to be effective. It has been found that oral administration of a liposomal composition comprising L-theanine has a profound effect on certain neurotransmitter related disorders even when delivered in surprisingly low concentrations.

The teachings of Keller et al. and Ueda et al. do not suggest applicant's invention. Applicant respectfully submits that there is no teaching in either reference that would lead one skilled in the art to combine their teachings. In short, the differences between applicant's claimed invention and the teachings of the cited references would be unobvious to one skilled in the art. Therefore, applicant respectfully requests that the Examiner withdraw this rejection.

Claims 7-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Blum (US 6,132,724) in view of Keller et al. (US 5,891,46). Applicant respectfully traverses this rejection and requests that it be withdrawn for the following reasons.

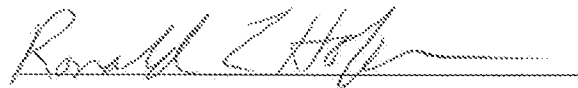
Blum highlights the unobviousness of applicant's invention. Theanine and 5-HTP are each known compounds. But, despite the extensive teachings in Blum, there is no teaching of

the use of either one in a liposomal encapsulated composition. The Examiner seeks to combine the teachings of Blum with Keller et al., but there is no suggestion in either reference that would lead to their combination and such combination is the result of an improper hindsight reconstruction of applicant's invention. Both references have lengthy disclosures that notably do not encompass applicant's invention. In short, one skilled in the art would not have been led to applicant's invention by these references.

In conclusion, applicant respectfully submits that all claims now pending in this application are in condition for allowance. It is believed that all of the rejections under §112 have been overcome by the present amendment and that the rejections under §103(a) have been shown to be improper. Therefore, an allowance of all claims is solicited.

July 6, 2007

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Ronald L. Hofer", is written over a horizontal line.

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